

Message Text

UNCLASSIFIED

PAGE 01 MILAN 00150 231559Z

70

ACTION HEW-06

INFO OCT-01 EUR-12 ISO-00 OES-05 RSC-01 MED-03 /028 W

----- 010475

R 231431Z JAN 75

FM AMCONSUL MILAN

TO SECSTATE WASHDC 3888

INFO AMEMBASSY ROME

AMEMBASSY NICOSIA

UNCLAS MILAN 0150

E.O. 11652: N/A

TAGS: ETRD EIND TBIO XX

SUBJECT: RECALL OF INCORRECTLY MANUFACTURED AND INCORRECTLY
LABELED MEDICAL DEVICE

REF: STATE 004097 (NOTAL)

1. MR. A. SABATO, MARKET MANAGER OF MILES ITALIANA DIVISIONE AMES, MILAN, INFORMED CONGEN THAT NOTICE TO QUARANTINE AND INSPECT (NOT RECALL) WAS RECEIVED FROM THE EUROPEAN HEADQUARTERS OF MILES LABORATORIES IN SLOUGH, ENGLAND BY TELEX ON OCTOBER 22, 1974. CONSEQUENTLY, THE FOLLOWING DAY SABATO ADVISED THE HOSPITALS WHERE THE BLOOD ANALYZERS ARE LOCATED AND THE MEDICAL REPRESENTATIVES EMPLOYED BY MILES IN ITALY TO CHECK THE ANALYZERS. A CHECK WAS ALSO MADE IN THE MILES LABORATORIES ON THOSE BLOOD ANALYZERS THEN IN STOCK. IN ALL CASES NO DEFECTIVE DIAL FACES WERE FOUND UPON INSPECTION.

2. SABATO ALSO ADVISED THE MILES REPRESENTATIVE IN CYPRUS (WHICH IS THE ONLY COUNTRY IN HIS AREA IN ADDITION TO ITALY WHERE THE BLOOD ANALYZERS ARE LOCATED). THIS ADVICE WAS EFFECTED BY TELEPHONE, AS NO OTHER MEANS OF COMMUNICATION WAS POSSIBLE BECAUSE OF THE THEN SITUATION IN NICOSIA. OF THE 2 BLOOD ANALYZERS THEN IN CYPRUS ONLY ONE WAS IN USE. THIS HAS BEEN CHECKED BY THE CYPRUS REPRESENTATIVE WHO IS

THE CYPRUS PHARMACEUTICAL ORGANIZATION LTD.

PAPAEELLINA HOUSE

KING PAUL I ST.

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PAGE 02 MILAN 00150 231559Z

P.O. BOX 1005

NICOSIA 118

NO DEFECTIVE DIAL FACES WERE FOUND UPON INSPECTION.

3. THE CONGEN EMPHASIZED THE WORDING OF THE REFTTEL,
I.E. RECALL AND NOT INSPECTION. MR. SABATO HAS PROVIDED THIS
OFFICE WITH A COPY OF THE TELEX OF OCTOBER 22, 1974 WHICH IN
FACT SPEAKS OF QUARANTINE AND INSPECTION AND EVENTUAL EXCHANGE
AND NOT RECALL.

AFTER OUR FIRST CONTACT WITH MR. SABATO HE HAS SPOKEN WITH HIS
EUROPEAN HEADQUARTERS IN SLOUGH FOR A CLARIFICATION. MR. SABATO
HAS NOW INFORMED US THAT SLOUGH REPLIED "RECALL MEANS TAKE
CORRECTIVE ACTION, AND THIS IS THE UNDERSTANDING WITH THE FDA."
FINA

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, RECALLS
Control Number: n/a
Copy: SINGLE
Draft Date: 23 JAN 1975
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1975MILAN00150
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Document Unique ID: 00
Drafter: n/a
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: D750026-0154
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Margaret P. Grafeld
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Status: NATIVE
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TAGS: ETRD, EIND, TBIO, XX, SP
To: STATE
Type: TE
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